

Application No. 10/663,568
Amendment dated: February 10, 2009
Reply to Office action of: November 14, 2008

REMARKS/ARGUMENT

Description of Amendments

Claims 25, 28-32, and 34-37 are pending. Claim 27 has been cancelled. Claims 25, 32, and 35 have been amended.

Claim 25 has been amended to incorporate the subject matter of Claim 27, and according, Claim 27 has been cancelled. Claims 32 and 35 have been amended to clarify that the coating is in a layer. No new matter has been added. Entry of the amendments is respectfully requested.

Status of the Application

The Examiner alleges that claim 36-37 deal with subject matter not “constructively” elected in the original presentation of claims. Applicants traverse.

Claims 36-37 are product-by-process claims. MPEP § 2113 states that “”[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.” Thus, when the Examiner states that “the originally claimed invention can be made by a different method than that of the method of claims 36-37,” this statement does not apply when considering patentability of the product, which in this case is an implantable medical device. Further, because only the products are considered for patentability, the Examiner has not made a *prima facie* case for restriction by showing that the products are independent or distinct from the invention originally claimed as discussed under MPEP§ 802.01 as follows:

The term "independent" (i.e., <**>unrelated<>) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. . . Two or more inventions are related (i.e., not independent) if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect. . . Related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art).

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Reconsideration and withdrawal of the restriction are respectfully requested.

First Rejection under 35 U.S.C. §103

Claims 25 and 28-31 and 35 have been rejected under 35 USC § 103(a) as being unpatentable over Hunter *et al.* U.S. Patent No. 5,886,026. Applicants traverse.

Claim 25 has been amended to include the limitation that the coating layer is free from any therapeutic substances. As the Examiner admits on page 6 of the Office action dated November 10, 2008, “Hunter does not [teach or suggest] that their coating layer is *free from* any therapeutic substances.” Independent claim 32 also has a similar limitation.

Having a coating layer that is free from any therapeutic substances is important because it allows for greater control of the release of the loaded microparticles containing the therapeutic substance. The use of microparticles allows for higher drug-loading at a particular target site. In addition, in the past, “drug release rates may also be inadequate since the rate at which the drug is released or delivered to the target site is a function of the chemical and/or biological properties of the polymer in which the drug is embedded.” (See specification, page 2, lines 25-28) Therefore, if the polymer itself is free from any therapeutic substances, there are no control issues to interfere with or compete with the microparticle portion of the drug delivery system.

Therefore, claim 25 is not obvious over Hunter *et al.* Additionally, claims 28-31 depend from claim 25 and are also not obvious for the reason above. Similarly, claim 35 depends from independent claim 32, which was not found to be obvious in view of Hunter *et al.* Therefore, dependent claim 35 is also not obvious in view of Hunter *et al.*

Second Rejection under 35 U.S.C. §103

Claims 27, and 32 have been rejected under 35 USC § 103(a) as being unpatentable over Hunter *et al.* U.S. Patent No. 5,886,026 as applied to claims 25, 28-31, 34 and 35 above and further in view of Wang (U.S. Patent No. 6,379,379). Applicants traverse.

As the Examiner admits on page 6 of the Office action dated November 10, 2008, “Hunter does not [teach or suggest] that their coating layer is *free from* any therapeutic substances.” The Examiner then cites Wang to make up this deficiency by stating that Wang teaches that the stent can have multiple layers of different polymers with the same or different drugs. However, Wang does not teach or suggest the limitations of independent claims 25 (which now incorporates claim 27) and 32.

Claim 25 requires “polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made, wherein the coating layer is free from any therapeutic substances.” This means that the therapeutic substances are embedded in the same coating layer that is free from any therapeutic substances, and the same coating layer comprises a polymer different than the polymer from which the particles are made. A similar argument may be made for independent claim 32. As mentioned in the section above, having a coating layer that is free from any therapeutic substances is important because it allows for greater control of the release of the loaded microparticles containing the therapeutic substance.

Wang teaches the use of multiple-layer coatings, for instance where one layer has a drug and the other layer doesn’t have a drug. (See col. 6, ll. 26-28). Even if the Examiner makes the argument that claim 25 is not limited to a single layer coating because of the word “comprising” in the claim, Wang fails to teach that one of the layers in the multiple-layer coating has all of the limitations of claims 25 and 32. Thus, Wang fails to teach or suggest claims 25 or 32.

Reconsideration and withdrawal of the rejection of claim 32 is respectfully requested.

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Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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| Date: <u>February 10, 2009</u> | <u>/RPA/</u> |
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